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10/566,411	01/30/2006	Fabio Rinaldi	27419310	5530

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EXAMINER	
SCHLIENTZ, NATHAN W	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,411	RINALDI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-12 are pending in the present application and are thus examined herein on the merits for patentability. No claim is allowed at this time.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03 April 2009 is being considered by the examiner.

Specification

The amendments to the specification filed 03 April 2009 have been entered.

Affidavit under 37 C.F.R. § 1.132

The declaration under 37 CFR 1.132 filed 03 April 2009 is insufficient to overcome the rejection of claims 1-12 as set forth in the Office action herein below because: The declaration shows treatment of 20 volunteers between the ages of 18 and 55 who signed a consent form indicating they had no pathologies during the period immediately preceding the study or in progress during the study. Therefore, Applicants argue that the invention is directed to maintaining the health and beauty of normal healthy skin. However, it is unclear what is encompassed by "pathologies". Skin begins to age when people are in their twenties. Therefore, clearly the population of subjects

tested includes persons with aging skin. Thus, it's not clear if aging skin is considered a pathology. Also, the declaration in combination with the specification may show that treating 20 patients between the age 18 and 55 increased skin hydration and elasticity values, but the specification does not limit the patient population to patients with "substantially healthy human skin". Applicants further argue that the declaration shows that the patient population did not have prolonged exposure to UVA and UVB rays. However, this limitation is not within the scope of the instant claims. The claims do not mention anything about exposure to UVA or UVB rays.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 1-4 state "substantially healthy human skin". However, the instant specification does not provide support for "substantially healthy human skin".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" in claims 1-4 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Raisfeld (US 4,507,321).

Raisfeld discloses topical or oral compositions comprising a polyamine, such as spermine or spermidine, which are useful to regulate, i.e., stimulate or inhibit, epithelial cell growth (Abstract; col. 2, ln. 68; col. 3, ln. 1, 27-33 and 58-68; and col. 3, ln. 1-19). Raisfeld further discloses examples wherein topical or oral formulations comprise spermine or spermidine (Examples 1, 2 and 4-11). See also claims 1, 2, 5, 8, 9, 13 and 14.

Response to Arguments

Applicants argue on pages 7-8 that the present invention is drawn to treating substantially healthy skin to improve hydration to maintain health and beauty of the skin (i.e. normal, unaffected, non-pathological conditions are concerned). Applicants argue that the prior art is drawn to treatment of skin in pathological conditions, or aged skin. However, the examiner respectfully argues that instant claims 1 and 2 merely state treating "substantially healthy human skin". As discussed above, substantially healthy human skin is a term of degree that is not defined by the specification or the claims. Therefore, stimulating epithelial cell regrowth in wound healing can encompass skin that is substantially healthy. Also, claims 3-12 are drawn to a composition wherein the intended use is to administer said composition to humans. However, the recitation of the intended use "for administration in humans with a restriction to improve hydration and maintain health and beauty of substantially healthy human skin and skin appendages" and "for administration in humans so as to improve at least one of the

following properties of substantially healthy human skin: hydration, elasticity, cell renewal" has not been given patentable weight to distinguish over Raisfeld because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Raisfeld discloses compounds that are the same as those claimed, they would be capable of performing the intended use, as claimed.

With regard to claims 1 and 2, Applicants claim improving hydration and maintaining health and beauty of the skin and skin appendages. In the absence of evidence to the contrary, administration of spermidine or spermine according to Raisfeld would inherently result in improving hydration and maintaining health and beauty of the skin. The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does

not make it novel, the identification and characterization of a prior art material also does not make it novel."

2. Claims 1-4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Charonis et al. (WO 94/12464; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Charonis et al. disclose polyamines which are useful for treating tissue aging (Abstract), wherein the composition is suitable for topical or oral administration (pg. 11, ln. 20-22), and the preferred polyamines include spermine and spermidine (claims 1 and 4-8).

Response to Arguments

Applicant's arguments are the same as above. Therefore, the examiners response above is incorporated herein by reference.

3. Claims 3, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ilenchuk et al. (WO 99/51213; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Ilenchuk et al. disclose the topical administration of polyamines in the palliative treatment of chronic diseases and disorders of epithelial tissue (Abstract). Ilenchuk et al. disclose that the use of polyamines for therapeutic treatment of tissue damage is known (pg. 12, ln. 33-35), wherein it is taught that polyamines regulate, stimulate or inhibit epithelial growth (pg. 13, ln. 1-11). Ilenchuk et al. further disclose that the

preferred polyamines include spermidine and spermine in the free base form or acid addition salt form (pg. 19, ln. 20, 21; and pg. 20, ln. 15-18), and the compositions are suitable for topical and oral administration (pg. 20, ln. 25-35). Ilenchuk et al. disclose several examples wherein spermine or spermidine is formulated into topical or oral administration formulations (pg. 22-27, Preparations 1-11). See also claims 1-8.

Response to Arguments

Applicant's arguments are the same as above. Therefore, the examiners response above is incorporated herein by reference.

4. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckart et al. (EP 0 884 046 A1; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Eckart et al. disclose cosmetic compositions with photoprotective properties, wherein the compositions comprise Vitamin E, Vitamin C, and at least one natural polyamine (Abstract). Eckart et al. disclose that the compositions are suitable for retention of elasticity and of moisture in the skin (col. 1, ln. 7-12). Eckart et al. further disclose that especially preferred natural polyamines are spermine and spermidine (col. 2, ln. 13-14); and that the compositions are formulated as cosmetic skin-care products (col. 4, ln. 42-44). Eckart et al. disclose an example wherein a sun protection balm was prepared comprising D-panthenol, Vitamin C, spermine, and tocopherol (Example 2). See also claims 1, 8 and 11.

Response to Arguments

Applicants argue on page 8 that Eckart et al. relate to a photo protective composition wherein a natural polyamine is only found to be a useful co-agent. Applicants argue on page 9 that Eckart et al. disclose treating skin affected by a pathological agent, i.e. UV irradiation. However, the examiner respectfully argues that the claims do not limit the skin to that which has not been exposed to UV irradiation. Also, the skin as disclosed in Eckart et al. is not damaged by the UV irradiation, but rather the composition prevents damage from the UV irradiation. Therefore, the skin is not inflicted with a pathological condition. Also, as discussed above, claims 3-12 are drawn to the composition and its intended use in not given patentable weight to distinguish over Eckart et al. Furthermore, topically administering the composition according to Eckart et al., which comprises spermine or spermidine, would inherently result in improving hydration and maintaining health and beauty of the skin.

5. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. (WO 98/06376; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Wolf et al. disclose a nail strengthening composition comprising tocopherol, pantetheine, pyridoxine, biotin and spermine (Example 1; and claims 18-20).

Response to Arguments

Applicants argue on page 8 that prior art that relates to nail strengthening and hair conditioning agents are even less relevant. However, the examiner argues that claims 3, 4, 8 and 12 are drawn to compositions, not methods of treating skin.

Therefore, the compositions according to claims 3, 4, 8 and 12 are anticipated for the reasons discussed above.

6. Claims 1-4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn et al. (WO 96/23490; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Hahn et al. disclose compositions and formulations containing polyamines for inhibiting skin irritation in animals (Abstract). Hahn et al. further disclose that the composition is for topical administration and comprises spermine or spermidine (claims 1 and 2).

Response to Arguments

Applicant's arguments are the same as above. Therefore, the examiners response above is incorporated herein by reference.

7. Claims 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsubara et al. (JP 2003/113047 A; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Matsubara et al. disclose a hair cosmetic preferably comprising spermine or spermidine (Abstract).

Response to Arguments

Applicants argue on page 8 that prior art that relates to nail strengthening and hair conditioning agents are even less relevant. However, the examiner argues that

claims 3, 4, 8 and 12 are drawn to compositions, not methods of treating skin. Therefore, the compositions according to claims 3, 4, 8 and 12 are anticipated for the reasons discussed above.

8. Claims 3, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Minoshima et al. (JP 07/268323 A; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Minoshima et al. disclose a pharmaceutical antioxidant preparation comprising spermine or spermidine, tocopherol and ascorbic acid (Abstract).

Response to Arguments

Claims 3, 4, 7, 8, 11 and 12 are drawn to compositions and as such their intended use is not given patentable weight to distinguish over Minoshima et al., as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 5, 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoshima et al. (JP 07/268323 A) in view of Henderson (WO 00/37087) and Ioannides (WO 02/15860; listed in the IDS filed 30 January 2006, but no copy was provided, so a copy is provided attached hereto).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Minoshima et al. teach a pharmaceutical antioxidant preparation comprising spermine or spermidine, tocopherol (Vitamin E) and ascorbic acid (Vitamin C) (Abstract).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Minoshima et al. do not teach the composition further comprising methyl sulfonyl methane, Vitamin B6, calcium d-pantothenate, biotin, zinc, copper and manganese amino acid chelates, and selenium, as instantly claimed. However, Henderson teaches that amino acid chelates of copper, zinc and manganese, and optionally selenium are known to reduce free radical cellular oxidative stress by strengthening and maintaining the activities of enzymes known to remove harmful superoxides, peroxides, and hydroxides (pg. 8, ln. 24-27). Henderson teaches that proper metabolic functioning of minerals such as copper, zinc and manganese in addition to or independent of selenium

play an important role in maintaining the function of oxidative enzymes that relate to oxidative bursts in neutrophils and macrophages, and in controlling or alleviating free radical cellular oxidative toxicity (pg. 10, ln. 11-20). Henderson further teaches that vitamins are essential for maintaining good health (pg. 11, ln. 19), and vitamins C, E, B6, biotin and pantothenic acid are advantageously added to a comprehensive dietary supplement; wherein Vitamins C and E also provide antioxidant function (pg. 12, ln. 12-32). Henderson teaches that the preferred amount in parts by weight of zinc is 1-25 x 10^{-3}, selenium is 1-75 x 10^{-6}, copper is 0.1-2 x 10^{-3}, manganese is 0.1-10 x 10^{-3}, Vitamin C is 10-500 x 10^{-3}, Vitamin E is 1-500 IU, Vitamin B6 is 0.1-20 x 10^{-3}, biotin is 25-200,000 x 10^{-6}, and pantothenic acid is 1-50 x 10^{-3} (pg. 11, ln. 1-14; and pg. 12, ln. 15-28).

Minoshima et al. do not teach the addition of methylsulfonylmethane to their pharmaceutical compositions. However, Ioannides teaches that methylsulfonylmethane (MSM) is added to ascorbic acid as an anti-inflammatory and to accelerate healing (pg. 25, ln. 13-16).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add vitamins and minerals to the formulations of Minoshima et al. to enhance the anti-oxidative properties and improve overall health, as reasonably taught by Henderson; as well as adding methylsulfonylmethane as an anti-inflammatory agent to accelerate healing, as reasonably taught by Ioannides.

With respect to the amounts of each component listed in instant claims 6 and 10, the examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 9-10 that the declaration shows that it was unexpected that spermidine and/or spermine could hold water at the stratum corneum of the epidermis in non-pathological or non-aged conditions. However, the examiner respectfully argues that claims 5, 6, 9 and 10 are drawn to compositions and the

intended use is not given patentable weight to distinguish over Minoshima et al. in view of Henderson and Ioannides.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616